



[BILLING CODE 4140-01-P]

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Submission For OMB Review; 30-Day Comment Request: Gulf Long-Term Follow-Up Study (GuLF STUDY)

SUMMARY: Under the provisions of Section 3507(a)(1)(D) of the Paperwork Reduction Act of 1995, the National Institute of Environmental Health Sciences (NIEHS), the National Institutes of Health, has submitted to the Office of Management and Budget (OMB) a request for review and approval of the information collection listed below. This proposed information collection was previously published in the Federal Register on November 7, 2013 on pages 66945-66946 and allowed 60-days for public comment. No public comments were received. The purpose of this notice is to allow an additional 30 days for public comment. The National Institute of Environmental Health Sciences (NIEHS), National Institutes of Health, may not conduct or sponsor, and the respondent is not required to respond to, an information collection that has been extended, revised, or implemented on or after October 1, 1995, unless it displays a currently valid OMB control number.

DIRECT COMMENTS TO OMB: Written comments and/or suggestions regarding the item(s) contained in this notice, especially regarding the estimated public burden and associated response time, should be directed to the: Office of Management and Budget, Office of Regulatory Affairs, OIRA_submission@omb.eop.gov or by fax to 202-395-6974, Attention: NIH Desk Officer.

COMMENT DUE DATE: Comments regarding this information collection are best assured of having their full effect if received within 30 days of the date of this publication.

FOR FURTHER INFORMATION: To obtain a copy of the data collection plans and instruments, or request more information on the proposed project, contact: Dr. Dale P. Sandler, Chief, Epidemiology

Branch, NIEHS, Rall Building A3-05, PO Box 12233, Research Triangle Park, NC 27709 or call non-toll-free number 919-541-4668 or E-mail your request, including your address to: Sandler@niehs.nih.gov. Formal requests for additional plans and instruments must be requested in writing.

PROPOSED COLLECTION: Gulf Long-Term Follow-Up Study (GuLF STUDY), 0925-0626, Expiration Date 01/31/2014 – REVISION, National Institute of Environmental Health Sciences (NIEHS), National Institutes of Health (NIH).

Need and Use of Information Collection:

The purpose of the GuLF STUDY is to investigate potential short- and long-term health effects associated with oil spill clean-up activities and exposures related to the Deepwater Horizon disaster, and to create a resource for additional collaborative research on focused hypotheses or subgroups. Exposures range from negligible to potentially significant; however, potential long-term human health consequences are largely unknown due to insufficient research in this area.

The study has enrolled 32,762 participants with a range of jobs/exposures, including participants who performed various types of clean-up-related work (“exposed”) and other who did not (“unexposed” controls). Of the 32,762 enrolled into the Full Cohort, 20,000 have been assigned to the Active Follow-up Sub-cohort, and 6,000 of these have been assigned to the Biomedical Surveillance Sub-cohort.

In order to minimize loss to follow-up, updated contact information will be collected yearly for the Full Cohort. Follow-up questionnaires will be administered biennially to the Active Follow-up Sub-Cohort to assess changes in health status and factors that could confound associations between exposures and outcomes. A supplemental mental health questionnaire will be administered repeatedly over a 2-year period to a subset of 4,600 participants in the Active Follow-up Sub-cohort to assess mental health trajectories among those affected by the oil spill and utilization of mental health services in the Gulf region. Participants in the Biomedical Surveillance Sub-cohort will be invited to take part in a comprehensive research-based clinical examination. The clinical exam provides an opportunity to carry out more comprehensive clinical testing and mental health evaluations than could be completed during the

baseline home visit. The exams will allow for a much more in-depth assessment of pulmonary, neurological, and mental health outcomes that may be associated with the Deepwater Horizon oil spill exposures and experiences.

OMB approval is requested for 3 years. There are no costs to respondents other than their time.

The total estimated annualized burden hours are 21,724.

Estimated Annualized Burden Hours

Type of Respondent	Form/Activity	Number of Respondents	Number of Responses per Respondent	Average Time per Response (in hours)	Total Burden Hour (for 3 years)	Annualized Burden Hour
Cleanup & non-Cleanup Workers	Annual Recontact Questionnaire	32,762	3	15/60	24,572	8,191
Cleanup & non-Cleanup Workers	Supplemental Mental Health Telephone Questionnaire	4,600	4	15/60	4,600	1,533
Cleanup & non-Cleanup Workers	Follow-up Telephone Questionnaire	20,000	2	30/60	20,000	6,667
Cleanup & non-Cleanup Workers	Clinical Exam	4,000	1	4	16,000	5,333

Dated: January 9, 2014

Joellen M. Austin,
Associate Director for Management.

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